

REMARKS

Claims 20-35, 37, and 47-55 are pending, with claims 48 and 51 withdrawn pending the allowance of a generic or a linking claim. By this Amendment, claims 20, 25, 28, 34, 47, and 50 are amended and new claims 56 and 57 are added. Support for the amendment to claims 20 and 47 can be found for example on page 8, lines 1-6, page 14, lines 14-19, page 24, lines 19-31, and page 34, lines 3-14 of the original application. Support for the amendment to claim 28 can be found for example on page 14, lines 14-19, page 13, lines 4-5 and page 15, lines 22-25 of the original application. Support for the amendment to claim 34 can be found for example on page 14, lines 14-19 of the original application. Support for claim 56 can be found for example on page 24, lines 19-31 and page 34, lines 3-14 of the original application. Support for claim 57 can be found for example on page 24, lines 19-31 of the original application. No new matter is introduced.

Objection to the Specification

The specification is objected to for failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner asserted that the specification fails to disclose each of the surface capillary fibers comprising a capillary along its outer surface running along at least a portion of the length of the surface capillary fiber. With all due respect, the Examiner's position is not clear, and Applicants strenuously maintain that the previous claims met the statutory written description requirement. For the purpose of facilitating prosecution only, independent claims 20, 28, 34, and 47 are amended to specify that each of the surface capillary fibers comprises at least one capillary along its outer surface. The support to this amendment to claims 20, 28, 34, and 47 can be found for example on page 14, lines 14-19 of the original application. Because the use of the "comprising" language, the claims mean the same thing before and after the amendment. The objection to the specification is nevertheless moot in view

of the amendments to the independent claims. Withdrawal of the objection is respectfully requested.

Objection to the Claims

Claims 20-35, 37, 47, 49, 50, and 52-55 are objected to because of informality. Independent claims 20, 28, 34, and 47 are amended based on the Examiner's suggestion. Claim 50 is objected to for insufficient antecedent basis. Claim 50 is amended to provide sufficient antecedent basis in the claim language. In view of the amendments, the objections to 20-35, 37, 47, 49, 50, and 52-55 are obviated. Withdrawal of the objection is respectfully requested.

35 U.S.C. §112 Second Paragraph Rejection

Claims 20-27, 53, and 54 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 20 and 25 are amended to clarify the claimed subject matter. In view of the amendments, the objections to 20-35, 37, 47, 49, 50, and 52-55 are obviated. Withdrawal of the objection is respectfully requested.

35 U.S.C. §102(e) Rejection

Claims 20, 21, 24, 26-31, 33-35, 37, 47, 49, 50, 54, and 55 are rejected under 35 U.S.C. §102(e) as being anticipated by Olsen et al. (U.S. Patent No. 7,326,196). Respectfully, Olsen does not teach all of the elements of Applicants' claimed invention. Olsen discloses filaments configured to form fluid pathways through at least one port of a catheter (Abstract of Olsen). The side ports of the catheter of Olsen appear to be important to achieve the intended fluid moving purpose. Although Olsen discussed using filaments with a variety of shape, Olsen does not teach or suggest using surface capillary fibers in particular or any advantage of using fibers

with surface capillaries. Because the catheter assemblies of Olsen is designed to move fluids, Olsen does not teach or suggest the filaments used can retain agents within the filaments and further will be able to subsequently release the retained agents in a controlled manner.

Independent claims 20 and 47 are amended to clarify the surface capillary fibers of the claimed invention are pre-loaded with bioactive agents. Only upon delivery and subsequent contact with bodily fluid the bioactive agent is controllably released through elution from the fibers. In contrast, Olsen teaches using filaments to facilitate movement of fluids through the catheter from exterior to the patient, and no elution from the fibers takes place. Olsen does not teach or suggest retain agents within filaments and subsequently releasing the agents. The Examiner cited line 60 of Col. 4 to line 5 of Col. 5 of Olsen as disclosing a bioactive agent being eluted in a controlled manner. Respectfully, Olsen cited antibiotic and/or analgesic for infusion, and not elution. The bioactive agent of Olsen therefore is neither pre-loaded, nor controllably released upon contact of bodily fluid or tissue. Olsen therefore does not disclose each and every element of the claimed invention in claims 20 and 47 and does not render claims 20 and 47 *prima facie* anticipated. Withdrawal of the rejection is respectfully requested. Applicants do not acquiesce with respect to the specific issues relating to the dependent claims, but these issues are not commented on further here due to the deficiencies with respect to the independent claims above.

Independent claim 28 is amended to clarify the capillaries of the surface capillary fibers has widths from about 1 micron to about 200 microns and the lengths of the surface capillary fibers are from about 500 microns to about 10 centimeters. The attachment means of the fibers are amended to cover association with an adhesive, heat bonding or chemical bonding. In contrast, Olsen relies on a mechanical device such as a retainer to maintain the filaments in place, and Olsen does not teach or suggest these types of attachment disclosed and claimed by Applicant. These different types of attachment are related to the inherent overall different

structures envisioned in Applicant's specification in contrast with the Olsen devices. Also, although Olsen discussed using filaments with a variety of shaped cross sections, Olsen does not teach or suggest using surface capillary fibers of specific lengths in particular or any advantage of using fibers with surface capillaries of the specified dimensions. Olsen therefore does not disclose each and every element of the claimed invention in claim 28 and does not render claim 28 *prima facie* anticipated. Withdrawal of the rejection is respectfully requested. Applicants do not acquiesce with respect to the specific issues relating to the dependent claims, but these issues are not commented on further here due to the deficiencies with respect to the independent claims above.

Independent claim 34 is directed to a medical device with a non-porous contoured surface for implantation. In contrast, the catheter assembly of Olsen does not have a surface that is contoured to match a portion of a structure within a patient and is apparently not for implantation. The Examiner asserts that the "surface is contoured to match a portion of a structure within the patient as a tubular sidewall (14) would match a blood vessel within a patient." With all due respect, that is not a correct description of the relationship of the structures. If a catheter can be delivered within a blood vessel, the catheter necessarily has a diameter significantly smaller than the diameter of the corresponding blood vessel or the catheter simply cannot be guided through the vessel. The smaller catheter structure will have a significantly smaller radius of curvature relative to the blood vessel, so the catheter cannot and does not have a structure matching the structure of a tissue structure in the patient. A catheter with matching contour of a surrounding blood vessel will not have a structure that can be inserted into a vessel and would at least cause significant damage to the surround vessel when forced into position. The Examiner's assertion of a catheter with contour matching the surrounding vessel will therefore render the catheter unsuitable to be used in performing a regular catheter type of activities. Olsen therefore does not disclose each and every element of

the claimed invention in claim 34 and does not render claim 34 *prima facie* anticipated. Withdrawal of the rejection is respectfully requested. Applicants do not acquiesce with respect to the specific issues relating to the dependent claims, but these issues are not commented on further here due to the deficiencies with respect to the independent claims above.

35 U.S.C. §103(a) Rejections

I. Claims 22, 32, and 52 are rejected under 35 U.S.C. §103(a) as being unpatentable over Olsen et al in view of DiCarlo et al. (U.S. Patent No. 6,929,626). Claim 22 depends from claim 20. Claim 32 depends from claim 31 which depends from claim 28. Claim 52 depends from claim 47. The deficiencies of Olsen with respect to the independent claims 20, 28, and 47 are described in detail above. Specifically, Olsen does not teach a bioactive agent preloaded onto the surface capillary fibers, and Olsen does not discuss the fiber properties of claim 28. While DiCarlo teaches bioactive agents associated with yarns and the like, the DiCarlo does not teach or suggest associating a bioactive agent with a surface capillary fiber or the like. Thus, neither Olsen nor DeCarlo alone or combined teach or suggest the pre-loaded association of a bioactive agent with a surface capillary fiber. Furthermore, Olsen teaches away from the combination since it teaches the delivery of a larger volume of bioactive agent through the catheter that would not be suitable for pre-loading. Thus, DiCarlo does not make up for the deficiencies of Olsen with regard to Applicants' claimed devices. Olsen and DiCarlo alone or combined therefore does not teach or suggest each and every element of the claimed invention in claims 20, 34, and 47 and does not render claims 20, 34, and 47 and their dependent claims 22, 32, and 52 *prima facie* obvious. Withdrawal of the rejection is respectfully requested. Applicants do not acquiesce with respect to the specific issues relating to the dependent claims, but these issues are not commented on further here due to the deficiencies with respect to the independent claims above.

II. Claim 25 is rejected under 35 U.S.C. §103(a) as being unpatentable over Olsen. Claim 25 depends from claim 20. As discussed in the above section, Olsen does not teach or suggest retain a bioactive agent in the filament for subsequent release. Olsen does not teach or suggest each and every element of the claimed invention and does not render claim 25 *prima facie* obvious. Withdrawal of the rejection is respectfully requested.

III. Claim 53 is rejected under 35 U.S.C. §103(a) as being unpatentable over Olsen et al. in view of Bucay-Couto et al. (U.S. Patent Application Publication No. 2003/0018306). Claim 53 depends from claim 20. Bucay-Couto discloses a reservoir having a polymer matrix disposed with antimicrobial agent. Olsen discloses a catheter assembly with filaments that assist in the transportation of fluids. Bucay-Couto does not make up for the deficiencies of Olsen discussed in detail above. Specifically, Olsen and Bucay-Couto alone or combined does not teach or suggest the usage of surface capillary fibers with a preloaded bioactive agent. Olsen in view of Bucay-Couto therefore does not teach or suggest each and every element of the claimed invention and does not render claim 53 *prima facie* obvious. Withdrawal of the rejection is respectfully requested.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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